Public Health Reasons

* (Denotes a critical item), critical item means a provision of the Rule, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazards.

37.110.204 FOOD SUPPLIES

(1) Source *
A primary line of defense in ensuring that food meets the requirements of 37.110.204. (1) is to obtain food from approved sources. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert for signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential health hazard.

Controlled processing is required for the safe preparation of food entering commerce. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food.

(2) Fluid Milk and Milk Products.
Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as ***Escherichia coli*** O157:H7, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption. Dairy products are normally perishable and must be received under proper refrigeration conditions.

(3) Molluscan Shellfish.
Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; and 3) mussels. The pathogens of
37.110.204(3) Molluscan Shellfish. (Continued)
concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving federal and state public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

Shellstock, Maintaining Identification.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf life of the product	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
Epidemiological investigation	10 days
Total	90 days

(4) Shell Eggs.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

Grade B or better eggs are required to be used in food

establishments. A license to grade eggs can be obtained from the Montana Department of Livestock. Graded eggs are candled so that

damaged eggs will be eliminated. Damaged eggs include those eggs which contain blood, are checked or cracked, or contain growth of embryo parts.
Liquid eggs are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in potentially hazardous foods. Freezing and drying of unpasteurized eggs will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes.

(5) Fish-Raw or undercooked
Lightly cooked, raw, raw-marinated and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking.

(6) Fish-source.
After December 18, 1997, all processors of fish were required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.
The seafoods implicated in histamine poisonings are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scrombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.
Ciguatera toxin is carried to humans by contaminated finfish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both

large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

(7) Game Animals.
The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

(8) Ice.
Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that is used as food or comes into contact with food to cool it must be as safe as drinking water.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

(9) Receiving Temperatures.
Temperature is one of the prime factors that control the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date.

(10) Frozen Foods
Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing during shipment may provide an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins.

37.110.206 FOOD STORAGE AND PROTECTION

(1) Preventing Potential Contamination.
Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes
37.110.206(1) Preventing Potential Contamination (Continued)
carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

Packages stored in direct contact with water or undrained ice that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

(2) Protecting Food from Cross Contamination. *
Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous foods. Raw animal foods must also be separated from each other because required cooking temperatures for each food are based on thermal destruction data and anticipated microbial load. Contamination with unanticipated additional pathogens can cause foodborne illnesses to occur.

(3) Cold Holding/Refrigerated Storage
The ability of equipment to maintain potentially hazardous foods at the required refrigeration temperatures is critical to food safety. Accurate temperature measuring devices in refrigeration units provide assurance that the equipment is functioning properly.

(4) Frozen Storage. *
Frozen food storage facilities must maintain foods in a solidly frozen state to assure that pathogens present in the foods are not allowed to grow.

37.110.206(5 & 6) Hot Holding Facilities
The ability of equipment to maintain potentially hazardous foods at required temperatures is critical to food safety. Improper hot holding temperatures continue to be a major contributing factor to foodborne illness. Therefore, it is very important to have adequate hot holding equipment with enough capacity to meet the demands of the operation.

(7) Emergencies. *
Emergency occurrences such as fire, floods, power outages or similar events can and do happen in Montana. It is the responsibility of the regulatory authority to determine the safety of the affected foods prior to their sale or service to the public if the food may be contaminated or potentially hazardous and held at improper temperatures.

37.110.207 FOOD PREPARATION

(1) Food Sinks
Food sinks must be maintained the same as any other food contact surface. Proper cleaning and sanitizing prevents unanticipated pathogens from being introduced into foods in this setting. Utilizing food sinks for handwashing or mop water disposal is prohibited to protect foods from the filth and toxic chemicals associated with those activities.

(2) Food Employee Requirements
See public health reasons under **37.110.210**

(3) Washing Raw Fruits and Vegetables
Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nonpotable water is used, the fruits and vegetables could become contaminated.
Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

On October 26, 1998 a voluntary guidance document that addresses practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" is available from FDA's Food Safety Initiative staff and also on the Internet at http://www.fda.gov.

37.110.207(4) Cooking Temperature Requirements. *
Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk, which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature. Greater numbers and varieties of pathogens generally are found on

poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 121 minutes after it has reached 54°C (130°F) is the same lethality attained as if it were cooked for 3 minutes after it has reached 63°C (145°F).

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and moisture content in the food aid with thermal destruction of pathogens.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

Consumers may request raw or undercooked foods of animal origin or foods containing these raw or undercooked animal foods. The department recommends that consumers be advised by written information on the menu or verbally by wait staff when foods containing raw or undercooked ingredients are being served. Included are items such as ceasar salad dressing with raw egg, hollandaise and béarnaise sauces with undercooked eggs and any other foods where the consumer may be unknowingly provided raw or undercooked foods of animal origin.

37.110.207(4) Cooking Temperature Requirements. * (Continued)
Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. The meat must be seared on both top and bottom surfaces utilizing a heating environment (eg., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 63°C (145°F) to achieve a cooked color change on all external surfaces.

Fresh fruits and vegetables that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 57.2°C (135°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

(5) Cooking in a Microwave Oven. *
The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes after microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction.

(6) Cooked and Refrigerated Foods Prepared for Immediate Service
There are many food items that do not require reheating to 165°F, but instead may be immediately served at any temperature in response to an individual consumers order. Properly cooked and refrigerated foods are not anticipated to have significant levels of pathogens or toxins present.
37.110.207(7) Cooling Methods for Potentially Hazardous Foods. *

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

(8) Reheating for Hot Holding. *
When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly held. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Although it takes as many as 1 million cells to cause foodborne illness, the generation time for ***C. perfringens*** is very short at temperatures just below adequate hot holding. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held below adequate hot holding temperatures, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

(9) Parasite Destruction by Freezing. *
Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

In response to information provided to the FDA office of Seafood, the Fish and Fishery Hazards and Controls Guide lists certain species of tuna as not being susceptible to parasites of concern and therefore are exempted from the freezing requirements for other fish species that are consumed raw.

(10) Hot and Cold Holding Requirements
Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 7°C to 57.2°C (45°F to 135°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Potentially hazardous food may be held in the “danger zone”for short time periods not exceeding four hours because there will be no significant growth or toxin production possible in that limited time.

(11) Thawing of Potentially Hazardous Foods. *
Improper thawing provides an opportunity for surviving bacteria that are present in frozen food to grow to harmful numbers and/or produce toxins. To prevent any chance of food borne illness, foods must be thawed properly.

37.110.207(12) Unapproved Additives
Use of unapproved additives, or the use of approved additives in

amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a HACCP plan which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

37.110.208 FOOD DISPLAY AND SERVICE

(1) Potentially Hazardous Food, Hot and Cold Holding.*
Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 7°C to 57.2°C (45°F to 135°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

(2) & (3) * Ice Dispensing & Food Contact with Equipment, Utensils and Wiping Cloths (only 3 is critical)
Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. Consumers or employees may also pass them on directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food

37.110.208(4) Vending Machines, Liquid Waste Products.
The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve

which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

(5) Molluscan Shellfish Tanks.
Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria. Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern.

(6) Ready-to-Eat, Potentially Hazardous Food, Date Marking.*
Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and like organisms may increase to hazardous levels in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of ***Listeria monocytogenes*** at 5°C (41°F) and 7°C (45°F). Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, potentially hazardous food may be kept at 5°C (41°F) a total of 7 days or at 7°C (45°F) a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at 5°C (41°F) but capable of maintaining it at 7°C (45°F) or below. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Potentially hazardous refrigerated foods must be consumed or discarded by the expiration date.

(7) Time as a Public Health Control. *
Potentially hazardous food may be held without temperature control for short time periods not exceeding four hours because there will be no significant growth or toxin production possible in that limited time.

37.110.208(8) Food Display for Consumer Self Service (only (8)(d) critical)
During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

Self-service operations of ready-to-eat foods provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

On or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants. Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. ***** Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

37.110.209 FOOD TRANSPORTATION

(1) Transporting Food
The protection of food from contamination and the maintenance of food at the proper temperatures are critical for the safety and quality of transported food. The special circumstances that arise during the transportation of food make the protection of the food and the maintenance of proper temperatures very difficult and correspondingly increase the possibility of contamination and microbial growth. For these reasons, special attention to sanitary requirements is essential during the food transportation process to provide the necessary protection to the consumer.
37.110.210 FOOD EMPLOYEES

(1) Food Employees, Diseases and Infections. *
A wide range of communicable diseases and infections may be
37.110.210(1) Food Employees, Disease and Infections.* (Cont.)
transmitted by infected food employees to consumers through food

or food utensils. Proper management of a food establishment operation begins with employing healthy people that maintain a high degree of personal cleanliness and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees.

For more information on restriction of food employees please refer to the Communicable Disease Rules ARM 16.28. subchapter 1-11 for the list of diseases that would cause food employees to be restricted or excluded from certain tasks in a food establishment.

(2) Personal Cleanliness
Dirty clothing may harbor diseases that are transmissible through food. Food employees may inadvertently, through their dirty clothing, contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

(3) Where to Wash Hands
Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing lavatory in order to help ensure that food employees effectively clean their hands. Handwashing lavatories are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Curbed cleaning sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks are used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

(4) When to Wash Hands. *
The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Rule are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.
37.110.210(5) Hand Sanitizers
This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and effective when

applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food.

(6) Minimizing Bare Hand Contact with Food. *
Even when properly washed, hands are not as clean as properly sanitized utensils, single use gloves or dispensing equipment. Whenever possible, bare hand contact with ready-to-eat-food must be minimized. Thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring pathogens to food.

(7) Food Employee Practices, Fingernail Maintenance.
The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry Prohibition.
Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing, Clean Condition.
Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Eating, Drinking, or Using Tobacco.*
Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food,
37.110.210(7) Eating, Drinking, or Using Tobacco.* (Continued)
prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and

food-contact surfaces may become contaminated.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

Hair Restraints
Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

(8) Unnecessary Persons
Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Rule requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

37.110.212 MATERIALS FOR EQUIPMENT AND UTENSILS

(1) Design and Construction
Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of
37.110.212(1) Design and Construction (Continued)
equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms

transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

(2) Cast Iron, Use Limitation
Cast iron is an alloy of iron and heavy metals which may leach into food if left in contact with acidic foods for extended periods of time. Heavy metal poisoning has resulted from such situations. The temporary or incidental contact that results from using cast iron as a cooking surface and for dispensing utensils used as part of an uninterrupted, short-term process is acceptable because of the brief contact time involved.

(3) Solder and Flux, Use Limitation
Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys. Lead has been linked to many health problems especially among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

(4) Wood, Use Limitation
The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

(5) Cutting Surfaces
Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

(6) Plastic surfaces
Surfaces that are subject to scratching or cutting may be difficult to clean and sanitize. Therefore, the surfaces may have to be re-conditioned, resurfaced or replaced.

37.110.212(7) Shells, Use Limitation
Mollusk and crustacea shells do not meet the Rule requirements for multiuse utensils. Therefore, such shells may be used only once as serving containers.

(8) Single-Service & Single Use Articles, Use Limitation
Articles that are not constructed of multiuse materials may not be reused, as they are unable to withstand the rigors of multiple

uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

(9) Lead in Ceramic, China, and Crystal Utensils, Use Limitation
Historically, lead has been used in the formulation and/or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

(10) Copper, Use Limitation.*
High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

(11) Galvanized Metal, Use Limitation. *
Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

37.110.213 EQUIPMENT AND UTENSIL DESIGN AND FABRICATION

(1) Equipment and Utensils, Durability and Strength
Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they cannot maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

(2) Food Contact Surfaces, Cleanability
The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces, which have imperfections such as cracks, chips, or pits, allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

(3) Bearings and Gear Boxes, Leakproof
It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

(4) Beverage Tubing, Separation
Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

37.110.213(5) Warewashing Sinks and Drainboards, Self Draining
The draining requirement in equipment components is needed to

prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

(6) Food-Contact Surfaces, Cleanability
The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

(7) Clean-in-Place Equipment, Cleanability
Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas that are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

(8) Fixed Equipment, Sealing for Cleanability
When the weight of the equipment exceeds 25 kg (50 pounds), it is no longer considered by Rule definition to be easily movable.

Consequently, this section is designed to ensure that fixed equipment is installed in a way that ensures that equipment that is subject to moisture is sealed.

(9) Temperature Measuring Devices.* (only (9)(a) critical)
The temperature measuring device must be placed in a location that is representative of the actual storage temperature of the

unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required.

***** Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

A permanent temperature measuring device is required in any unit storing potentially hazardous food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed rule requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Rule requirements to ensure accurate readings. The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

(10) Nonfood-Contact Surfaces

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

37.110.213(11-14) Ventilation Hood Systems, Drip Prevention, Function

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single

service and single use articles that are subjected to such drippage are no longer clean.

(15) Food Equipment, Acceptability
Food equipment that meets commercial standards that are certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program will be deemed to comply with this Rule. All other equipment shall be approved on a case-by-case basis. Home type appliances do not meet commercial standards and are not to be used in a licensed food service establishment, but may be permitted by a sanitarian while in the plan review stage, if they meet the intent of the Rule.

37.110.214 EQUIPMENT INSTALLATION AND LOCATION

(1) Location away from Sewer and Water Lines
Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

(2) Fixed Equipment, Spacing and Sealing
The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

(3) Equipment, Easily Movable
When the weight of the equipment exceeds 23 kg (50 pounds), it is no longer considered by rule definition to be easily movable. Consequently, this section sets criteria for easily movable equipment to facilitate cleaning.

37.110.214(4) Floor Mounted Equipment
The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be

necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

(5) Equipment Spacing and Sealing
This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;
2. Ensures that equipment that is subject to moisture is sealed;
3. Prevents the harborage of insects and rodents; and
4. Provides accessibility for the monitoring of pests.

(6) Aisles and Working Spaces
Equipment and tables shall be spaced so that there is room for employees to do their work properly. This issue is most appropriately addressed in the plan review stage.

37.110.215 EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION

(1-3) Cleaning of Equipment and Utensils. *
The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the
37.110.215(3) Cleaning of Equipment and Utensils. * (Continued)
development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

(4) Food Contact Surfaces of Cooking Devices
Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encursted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in 37.110.215(1-3).

(5) Non-food Contact Surfaces of Equipment
The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

(6-8) Wiping Cloths, Separation and Use Limitation
Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

(9) Sponges, Use Limitation
Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.
37.110.215(10) Manual Warewashing, Sink Compartment Requirements
The 3-compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and
3. Sanitization.

(11) Drainboards, Capacity
Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

(12) Precleaning of Utensils and Equipment
Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

(13) Manual Washing, Rinsing & Sanitizing*(only (13)(d) critical)
Cleaning of equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by *** sanitization**. It is important to rinse off detergents, abrasives, and food debris after the wash step to avoid diluting or inactivating the sanitizer. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

(14) Sanitization Methods. *
Effective sanitization procedures destroy organisms of public health importance that may be present on food equipment or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before
37.110.215(14) Sanitation Methods. * (Continued)
being sanitized to allow the sanitizer to achieve its maximum benefit.

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time that hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as

temperature or chemical concentration, are used in combination with time to deliver effective sanitization.

(15) Hot Water Sanitization Facilities. *
Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

(16) Chemical Sanitizer Test Kits/Concentration
Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:
1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and
2. Too much sanitizer in the final water could be toxic.

(17) Warewashing Equipment, Good Repair
Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Rule requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. A chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.
37.110.215(18) Mechanical Warewashing Equipment, Sanitization Pressure
If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

(19) Warewashing Machines, Temperature Measuring Devices
The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must

be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

(20) Warewashing Machines, Internal Baffles
The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

(21) Drainboards Provided
Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

(22) Dishware, Flushed and Scraped
Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

(23) Chemical Sanitization. *
The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the
37.110.215(23) Chemical Sanitation. * (Continued)
concentration of the chemical sanitizer solution.

(24-25) Hot Water Sanitization Temperatures. *
If the temperature of the hot water delivered to the warewasher manifold is inadequate to effect sanitization, surviving pathogenic organisms could contaminate equipment and utensils. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. Verification that adequate sanitization is achieved is provided through an irreversible registering temperature indicator.

(26) Warewashing Equipment, Cleaning Frequency
During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of

contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment at least once a day or more often when necessary.

(27) Equipment and Utensils, Air-Drying Required
Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

(28) Warewashing Backup Plan. *
It is important to have a plan in place when equipment fails to operate correctly. This plan could include use of single-service utensils or having a manual three-compartment sink in place and ready to use in case of failure of the mechanical system. The regulatory authority must approve the plan.

37.110.216 EQUIPMENT AND UTENSIL STORAGE

(1) Equipment Contamination/Handling
The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food-contact and lip-contact surfaces.

(2) Equipment and Utensil, Storage
Clean equipment and multiuse utensils which have been cleaned and sanitized can become contaminated before their intended use in a
37.110.216(2) Equipment and Utensil, Storage (Continued)
variety of ways such as through water leakage, pest infestation, or other unsanitary condition.

(3) Air Drying Required, Equipment and Utensils
Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

(4) Proper Storage of Equipment and Utensils
Storage and handling procedures for cleaned and/or sanitized equipment and utensils must be adapted to the protective storage requirements imposed by the varied storage conditions encountered in the general storage, storage incidental to food preparation or service, and the storage environment specified by consumer self-service.

(5) Storage of Single Service and Single-Use Articles
The improper storage of single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

(6) Single Service, Handling and Dispensing
The improper handling and dispensing of single service items may allow contamination before their intended use. Contamination can be caused by improper handling or dispensing of the item. Food service employees must be trained to handle, store and properly dispense single service items so that they do not become contaminated.

(7) Single Service Tableware, Handling
The presentation and/or setting of single-service and single-use articles shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

(8) Prohibited Storage Areas
The improper storage of clean and sanitized equipment, utensils, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials,
37.110.216(8) Prohibited Storage Areas (Continued)
litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

37.110.217 WATER SUPPLY

(1) Water Supply, Approved System, Source. *
Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

Inadequate water systems may serve as vehicles for contamination of food or food- contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is

protected.

(2) Hauled Water
Water provided by a Water Hauler must meet the requirements administered by the Department of Environmental Quality.

(3) Bottled Drinking Water. *
Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

(4) Water Under Pressure
Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

(5) Steam
Steam that is used for cleaning and sanitizing equipment must also be free from boiler additives and chemicals that would contaminate clean equipment. Hoses used to deliver steam must be approved for food service.

37.110.217(6) Water Reservoir of Fogging Devices, Cleaning. *
Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila.*** This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

(7) Drinking Water Standards, Quality
Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

(8) Sampling of Water Supplies

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

37.110.218 SEWAGE

(1) Approved Sewage Treatment System. *
Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper treatment of human wastes greatly reduces the risk of fecal contamination. This Rule provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

(2) Standards, Sewage Treatment Systems, Design and Construction
Sewage treatment systems must meet requirements established by law. Proper treatment of human wastes reduces the risk of fecal contamination. This rule is intended to ensure that wastes will not contaminate ground surfaces or water supplies, pollute surface waters, be accessible to children or pets, or allow
37.110.218(2) Standards, Sewage Treatment Systems, Design and Construction (Continued)
rodents or insects to serve as vectors of disease from this source.

(3) Operation and Maintenance
Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other unsanitary conditions that may attract insects and other vermin.

37.110.219 PLUMBING

(1) Cross-Connections. *
Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

(2) Non-potable Water. *
Food establishments may use non-potable water for purposes such as air-conditioning or fire protection. Non-potable water is not monitored for bacteriological or chemical quality or safety, as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as non-potable waterlines and inspection for cross connections are examples of safety precautions.

(3) Backflow Prevention Devices, When Required. *
The delivery end of hoses attached to hose bibs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bib to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

37.110.219(4) Grease Trap, Location
Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

(5) Garbage Disposal, Installation and Maintenance
Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food contact surfaces. Proper maintenance is important to the operation of the disposal.

(6) Backflow Prevention, Air Gap. *
Direct connections between sewage systems and drain lines from equipment containing food, portable equipment or utensils provides an opportunity in the event of a sewage back up, to contaminate these items with sewage.

37.110 220 TOILET FACILITIES

(1-7) Toilets and Urinals

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

(8) Toilet Tissue, Availability, Waste Receptacle
To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand. Waste receptacles at handwashing sinks are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

37.110.220(9) Venting of Toilet Rooms
When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

37.110.221 HANDWASHING FACILITIES

(1) Handwashing Facilities
Because handwashing is such an important factor in the prevention of foodborne illness, sufficient handwasing sinks must be available to make handwashing not only possible, but also likely.

(2) Customer use of Handwashing Facilities
Licensed food service establishments are different from our homes, we must control and limit who has access to the kitchen areas. Pathogens are spread by many different means. Limiting access to food preparation areas is one means of controlling entrance of pathogens to food. Customers must be provided with handwashing facilities that are separate from food preparation and other areas listed.

(3)* & (4) Handwashing Facilities, Location and Placement

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Handwashing sinks that are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the sink unavailable for regular employee use. Nothing must block the approach to a sink thereby discouraging its use, and the sink must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

(5) Service Sinks Used as Handwash Sinks, Limitation
Handsinks are expensive to install and some establishments may be limited for space to install handsinks that are accessible. This rule is in place to allow existing service sinks and utensil washing sinks to be used as handwash sinks if properly equipped, maintained, located and available.

(6) Handwash Sinks, Prohibited Uses
Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Wastewater must be disposed of

37.110.221(6) Handwash Sinks, Prohibited Uses (Continued)
in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal, not a sink that is used as a handwashing sink.

(7) Handwashing Sinks, Water Temperature and Flow
Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

(8-10) Maintaining and Using Handwashing Facilities
Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

37.110.222 GARBAGE AND REFUSE

(1-10) Containers, Maintenance, Burning
Proper storage and disposal of garbage and refuse are necessary

to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids
37.110.222(1-10) Containers, Maintenance, Burning (Continued)
or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents.

Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.
Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Alternative means of solid waste disposal (burning) must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

37.110.223 INSECT AND RODENT CONTROL

(1) Controlling Pests. *
Insects and other pests are capable of transmitting disease to

man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

(2) Insect Control Devices, Design and Installation.
Insect electrocution devices are considered supplemental to good

sanitation practices in meeting the Rule requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

37.110.223(3) Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.
Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

(4) Rodent Bait Stations.*
Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

(5) Tracking Powders.*
The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

(6) Outer Openings, Protected.
Insects and rodents are vectors of disease-causing microorganisms that may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

37.110.225 FLOORS

(1) Surface Characteristics.
Floors that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

(2 & 3) Floor Carpeting, Restrictions and Installation.
Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely. Sawdust and wood shaving used to be used in meat shops and is now prohibited.

37.110.225(4) Floors Drains
When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, thereby preventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as ***Listeria monocytogenes***.

(5) Floor Covering, Mats and Duckboards.
Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

(6) Floor and Wall Junctures, Coved, and Enclosed or Sealed.
When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing.

(7) Utility Lines.
Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding utility lines are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

37.110.226 WALLS AND CEILINGS

(1) Good Repair
Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned.

(2) Surface Characteristics.
Walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

(3) Walls and Ceilings, Studs, Joists, and Rafters.
Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

(4) Utility Lines.
Requirements and restrictions regarding exposed utility lines are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

37.110.226(5) Attachments.
Wall and ceiling attachments that are of smooth construction, nonabsorbent and in good repair can be easily and effectively cleaned.

(6) Covering Materials.
Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joist, and rafters are intended to ensure the cleanability of these surfaces.

37.110.227 CLEANING PHYSICAL FACILITIES

(1) Cleaning, Frequency and Restrictions.
Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

(2) Service Sinks, Availability.
A utility sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A utility sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and

food preparation and warewashing areas.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Wastewater must be disposed of in a sanitary manner that will not contaminate food or food equipment. A utility sink or curbed cleaning facility with a drain allows for such disposal.

(3) Service Sinks Used as Handwash Sinks, Location
In allowing the use of service sinks as handwash sinks, the Food

37.110.227(3) Service Sinks Used as Handwash Sinks, Location (Continued)
Code Task Force Committee recommended separation from areas where these sinks may cause contamination of food and utensils to occur.

37.110.228 LIGHTING

(1 & 2) Intensity.
Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

(3 & 4) Lighting, Protective Shielding.
Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

37.110.229 VENTILATION

(1-3) Adequate Ventilation
If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an unsanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard. The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage

are no longer clean.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

37.110.229(1-3) Adequate Ventilation (Continued)

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.
Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

37.110.230 DRESSING ROOMS AND LOCKER AREAS

(1 & 2) Conditions

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

37.110.231 TOXIC MATERIALS

(1) Presence Limitation.*

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and

proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

37.110.231(2) Original Containers, Manufactures Label.*
The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

(3) Working Containers, Common Name.*
It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

(4) Categories of Toxic Materials
Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Failure to properly identify, use and store chemicals can be dangerous.

(5) Chemical and Toxic Storage, Separation.*
Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

(6) Sanitizers, Criteria.*
Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used properly. Large concentrations of sanitizer can be harmful because residues of the materials remain.

(7) Poisonous or Toxic, Materials Use.*
Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated
37.110.231(7) Poisonous or Toxic, Materials Use.*(Continued)
instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toaxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacture on the material’s label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

(8) Medicines, Restrictions and Storage. *
Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage. There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

(9) First Aid Supplies Storage.*
First aid supplies for employee use must be identified and stored

in accordance with the requirements of this Rule in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

37.110.232 PREMISES

(1) Cleaning, Frequency and Restrictions.
Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A
37.110.232(1) Cleaning, Frequency and Restrictions (Continued)
regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

(2) Outdoor Walking and Driving Surfaces, Graded to Drain.
If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

(3) Maintaining Premises, Unnecessary Items and Litter.
The presence of unnecessary articles, including equipment that is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

(4) Unnecessary Persons
Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Rule requirements, the person in charge establishes an important barrier to food contamination.

(5) Private Homes and Living or Sleeping Quarters, Use Prohibited.
Areas or facilities that are not compatible with sanitary food establishment operations must be located and/or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

(6) Use of Laundry Facilities.
Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

37.110.232(6) Use of Laundry Facilities (Continued)
Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

(7) Linen Storage
Laundered linens can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other unsanitary condition.

(8) Storage of Soiled Linens.
Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

(9) Storing Maintenance Tools.
Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

(10) Prohibiting Animals.*
Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with support animals are required under ARM 37.110.210(4) to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

(11) Live Animals
A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.
Under Title III of the ADA, privately owned businesses that serve

the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars

37.110.232(11) Live Animals (Continued)
or harnesses. Some, but not all, are licensed or certified and have identification papers. Certification is currently not required in Montana.
Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the federal agency which has the lead in these matters, in documents such as, "Commonly Asked Questions About Service Animals in Places of Business"; "The Americans with Disabilities Act Questions and Answers"; "A Guide to Disability Rights Laws"; and "Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement." The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://www.usdoj.gov/crt/ada/adahom1.htm.

37.110.236 TEMPORARY FOOD SERVICE ESTABLISHMENTS

(1-14) Temporary Food Service Establishments. * (3,8,10 & 11 only)
Food served from temporary establishments is subject to the same potential for contamination as that served in fixed food service establishments as well as the additional potential for contamination resulting from specific conditions associated with temporary establishments. While recognizing the limited capability of most temporary operations, it is necessary for the protection of public health to regulate closely the construction and operational methods of such establishments. Due to this limited food protection capability, most temporary food service establishments must be restricted to the service of prepackaged and preprepared foods, or allowed only limited food preparation functions. The degree of such restrictions must be in direct relation to the capacity for food protection demonstrated by the construction of a temporary establishment and its equipment.

37.110.238 LICENSES

(1) Licensing
Licenses issued by the department indicate that an individual owner/operator of an establishment has met the minimum applicable public health requirements of this subchapter. Licenses are not transferable, meaning that the license is tied to both the

owner/operator and the facility. Posting licenses provides proof to patrons and health authorities that the establishment has been reviewed and approved. Operation without a valid license can provide no assurances of safety or approval.

37.110.238(2)-(4) Licensing

Application and approval procedures require certain information to be submitted to the department. Inspections performed by qualified persons verify the acceptability of a given establishment in light of this subchapters requirements.

(5)-(10) Procedures for license revocation establish a consistent procedure statewide in the event of serious or repeated violations, or interference with authorized persons in performance of duty. Hearings and plans of correction give the licensee and regulatory authority an opportunity to resolve issues prior to final revocation of the license.

(11) The requirements of other state, federal and local agencies can and do apply to food service establishments. This rule subsection serves to advise parties of this fact.

37.110.239 INSPECTIONS

Food Service Inspections

(1) A principal goal to be achieved by food establishment inspections is to prevent foodborne disease. Inspection is the primary tool a regulatory agency has for detecting procedures and practices which may be hazardous and taking actions to correct deficiencies. The requirements of this subchapter provide inspectors scientifically based rules for food safety.

It is the intent of the Rule that food service establishments to be inspected at least 2 times per year unless they qualify for a modified inspection program which has been approved by the department. This may mean that the establishment is under a reduced inspection schedule or it may mean that the establishment has more frequent inspections due to the types of food served, the preparation steps these foods require, the volume of food served, the population served, and previous compliance history.

The rational allocation of inspection resources to target the highest risk establishments with more inspection time and the lowest risk establishments with less, is a risk based approach to assuring food safety. Risk categorization allows establishments to be ranked by considering risk factors and creating a variable inspection frequency for each risk type.

(2) 50-50-302 of the Montana Code Annotated states that state and local health officers and sanitarians and sanitarians-in-training must be provided free access to licensed establishments at all reasonable times for the purpose of conducting inspections and

investigations required by the rules.

37.110.239(2) Inspections (Continued)
It is vital for inspectors to have free access to licensed establishments to ask questions of the person in charge and have access to records on food and food employees in order to determine compliance with the Rule.

(3) The inspection report form is the official department document regarding compliance of the food establishment with Rule requirements.

The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment at the time of inspection and to convey compliance information to the licensee or person-in-charge at the conclusion of the inspection. Such a report is required to be completed for routine, follow-up, and investigative inspections. Completed inspection reports are public documents and are made available to the public upon request.

(4) Timely follow-up inspections to verify correction of critical item violations are mandated under the Rule. These inspections verify that the critical items cited during the original inspection have been corrected or determine the course of corrective actions. Consistent follow-up inspections to assure correction of violations is the Regulatory Authorities commitment to public health protection and equitable enforcement. Other violations may have a longer period for correction as specified by the inspecting authority but prior to the next regular inspection.

(5) 50-50-209 of the Montana Code Annotated states that the department may cancel a license if it finds, after proper investigation, that the licensee has violated this chapter or a rule effective under this chapter and the licensee has failed or refused to remedy or correct the violation. This statement is on the inspection form to keep the licensee informed. Violations which are classified as imminent health hazards in Rule warrant immediate actions up to and including cessation of food service operations.

(6) The specific purpose of the follow-up inspection is to determine if critical violations detected during the initial inspection have been corrected. It may also be the basis for further compliance actions if remedial actions by the licensee are not effective.

37.110.240 EXAMINATION AND CONDEMNATION OF FOOD

Examination and Condemnation of Food, (only 4 critical)
(1)-(4)* In the event of discovery of food that is misbranded, adulterated, poisonous, deleterious to health, etc., the regulatory authority is charged with the responsibility of handling such foods as specified in this Rule. The acceptable procedures under specified circumstances are listed in this Rule. Foods that pose a serious threat to public health must not be allowed to be served in food service establishments.

37.110.241 PLAN REVIEW

Review of Plans
(1)-(2) Submitting properly prepared plans and specifications prior to beginning the construction, remodeling or conversion of a structure intended for use as a food service establishment is useful for many reasons. The operator is assured upon approval of the plans that the facilities will initially meet the requirements of the subchapter without significant additions or changes that, if needed after construction is completed, can be quite costly. The regulatory authority is able to assure compliance with the subchapter and provide support and advice to the operator. Changes to approved plans need the approval of the regulatory authority for the same reason.

(3) Existing buildings may or may not meet current requirements. The language in this subsection gives the regulatory authority the latitude to waive the plan review requirement, if no structural modifications are involved.

(4) This regulation is not the only regulation that is important to plan review. There are also many other regulations that must be met. They may include: building codes, fire codes, plumbing, electrical, mechanical codes, and fire life safety codes. City or county codes may also play a part in the plan review process.

(5) Inspections determine the food establishment’s compliance with Rule. Pre-operational inspections are conducted to ensure that the establishment is built or remodeled in accordance with the approved plans and specifications. These are usually scheduled inspections to meet with specific personnel or management from the establishment to discuss compliance with the Rule.

37.110.242 PROCEDURE FOR SUSPECTED DISEASE TRANSMISSION

(1) Suspected Disease Transmission, Procedure. *
Investigation of food borne illness is an integral part of
37.110.242 Suspected Disease Transmission, Procedure. * (Continued)
protecting public health when a food borne outbreak occurs. The procedures are in place for investigation when there is reasonable

cause to believe that illness possibly originated in a food establishment. Restriction or exclusion of employees from the food establishment are necessary steps to prevent further spread of illnesses. Laboratory examination of food employee body discharges may help determine the pathogen that is the cause of illness.

37.110.243 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEATH ATHORITIES

Minimum Performance Requirements for Local Health Authorities
Local health authorities receive a portion of the license fees collected by the department as long as minimum performance is demonstrated. This rule sets the minimum performance criteria.

37.110.251 SEPARABILITY

Separability
This Rule is standard language designed to retain subsections of the Rule should others be found to be invalid.

37.110.252 HIGHLY SUSCEPTIBLE POPULATIONS

(1) & (2) Highly Susceptible Populations. *
The rule provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

Salmonella often survives traditional preparation techniques. It survives in lightly cooked omelets, French toast, stuffed pasta, and meringue pies. Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk of foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products.

37.110.253 VARIANCE OF THE RULES

(1)- (5)* Variance Proposals, (only 5 critical)
The variance provision of this rule has been provided as a tool for industry to submit their requests to waive certain requirement of this Rule. As technology advances and new types of processes and

equipment are introduced, industry will have a continuous path to waive or modify the Rule requirements as long as public health hazards are adequately controlled and addressed.

37.110.254 SUBMITING A HACCP PLAN

Submission of a HACCP Plan. *
This Rule outlines what processes require a HACCP plan and provides specific requirements regarding reduced-oxygen packaging.
From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

During the past decade, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

37.110.255 CONTENTS OF A HACCP PLAN

HACCP Plan (Contents). *
Essentially, HACCP is a system that identifies and monitors specific foodborne hazards -- biological, chemical, or physical properties -- that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan.
37.110.255 Contents of a HACCP Plan. *(Continued)
Food processing operations at retail food establishments such as reduced oxygen packaging and curing and smoking under this rule are required to develop and implement a HACCP plan for that part of the operation.

In order to provide a consistent application of HACCP in Montana, this rule provides the needed detail for a plan submittal.

37.110.256 MOBILE FOOD SERVICE RULE

(1 - 8) Mobile Food Service. * (only (3) & (4) are critical)
In addition to hazards created by the transport and service of food from a mobile food unit, food served from such units is subject to the same potential contamination as that served in other food service establishments. This means that a mobile food unit must be regulated in the same manner, and provide to the consumer the same degree of food protection offered by any food service establishment. Those operations that are restricted by equipment limitations must be limited to the service of those foods for which they can provide sufficient protection according to the requirements of this rule.

More latitude is given to local sanitarians in the review of mobile units to restrict or limit the foods being served, restrict how far a mobile unit may travel to an event based on menu and equipment to provide the same degree of food protection offered by any food service establishment.

37.110.257 PUSHCART RULE

(1- 3) Pushcarts. * (only (3) (c) & (d) are critical)
Pushcarts offer limited menus to the consumer but must be regulated and provide to the consumer a safe food product. Pushcarts are not equipped with all of the facilities required by the rules for food service operations, but nonetheless must provide a safe product for the consumer.

37.110.258 SEMIPERMANENT FOOD SERVICE ESTABLISHMENTS

(1- 2) Semipermanent Food Service Establishments
Semipermanent establishments operate under the rule for Mobile food service establishments with the exception that they have access to a restroom adjacent to their location for employees use. Those operations that have a limited menu and can operate out of a small environment may qualify under this rule, subject to the local authorities restrictions.

37.110.259 PERISHABLE FOOD VENDING MACHINES

(1- 2) Perishable Food Vending Machines
The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods are vended in a hermetically sealed state to ensure

product safety. Once the original seal is broken, the food is vulnerable to contamination.

Failure to store potentially hazardous food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Rule requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Rule requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control", provides a limited amount of time that the ambient temperature of a machine may exceed rule requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.